

**United States Court of Appeals
FOR THE EIGHTH CIRCUIT**

No. 98-2851

National Bank of Commerce (of	*	
El Dorado, Arkansas), Conservator	*	
of the Estate (only) of John McDougal;	*	
John McDougal, Individually;	*	
	*	Appeal from the United States
Appellants;	*	District Court for the
	*	Eastern District of Arkansas.
v.	*	
	*	
Associated Milk Producers, Inc.;	*	
	*	
Appellee.	*	

Submitted: June 17, 1999

Filed: September 10, 1999

Before BOWMAN and HEANEY, Circuit Judges, and LONGSTAFF, District Judge.¹

HEANEY, Circuit Judge.

The sole question before us on appeal is whether the district court abused its discretion in refusing to admit into evidence plaintiff John McDougal's proffered expert testimony that he developed laryngeal cancer as a result of exposure to aerosolized milk

¹The Honorable Ronald E. Longstaff, United States District Judge for the Southern District of Iowa, sitting by designation.

containing aflatoxin M-1 (AFM) in a cheese plant at which he was employed for a period of fifteen months. Although the question is not free from doubt, we find no abuse of discretion.

I.

Defendant, Associated Milk Producers, Inc. (AMPI), is a cooperative of dairy farmers operating in fourteen states in the Midwest and Southwest. AMPI uses tanker trucks to pick up milk from its dairy farm members and deliver it to Grade A milk bottling companies and cheese-making companies, including Hills Valley Foods in Batesville, Arkansas.

John McDougal was employed at Hills Valley Foods from July 26, 1990 to October 31, 1991. During that time period, AMPI delivered many truckloads of milk to Hills Valley Foods, five of which contained AFM in excess of the .5 parts per billion level permitted by the Food and Drug Administration.² AFM is a potent

²The following milk loads from AMPI were tested and found to have the listed aflatoxin contamination. Only five of these were delivered to Hills Valley Foods:

<u>Date</u>	<u>Test Result</u>	<u>Date</u>	<u>Test Result</u>
10-27-90	0.7	4-8-91	1.0
10-28-90	0.5	4-9-91	0.6
12-10-90	3.9	4-17-91	1.0
12-11-90	5.0	4-17-91	1.0
12-12-90	3.9	5-28-91	5.0
12-16-90	0.8	6-3-91	2.5
2-11-91	0.5	6-4-91	1.2
3-18-91	1.0	6-5-91	4.8

(Appellant's App. at 24.)

hepatocarcinogen (Tr. at 160-61). It is undisputed that McDougal was exposed to aerosolized milk particles from these truckloads of milk containing AFM. On February 27, 1995, McDougal was diagnosed as having laryngeal cancer and had surgery for the removal of the cancer. The surgery left him unable to speak or breathe without the use a tracheal tube.

In June 1995, McDougal learned that four AMPI employees pled guilty in federal court for the distribution of and conspiracy to distribute contaminated milk in interstate commerce. After learning of the guilty pleas, McDougal commenced an action against AMPI in the United States District Court for the Eastern District of Arkansas, alleging that his laryngeal cancer had been caused by the aerosolized milk particles containing AFM. In the course of the proceeding, McDougal's counsel obtained several expert witnesses in order to establish that McDougal's laryngeal cancer was caused by his exposure to the AFM while employed at Hills Valley Foods. AMPI filed a motion to exclude McDougal's expert causation testimony, asserting that the testimony failed to meet the admissibility requirements set forth in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). After a six-day hearing with submission of briefs and oral argument, the district court, in a seventy-seven page opinion, excluded the testimony of McDougal's experts and granted AMPI's motion for summary judgment. See National Bank of Commerce v. Associated Milk Producers, Inc., 22 F. Supp.2d 942 (E.D. Ark. 1998). It did so on the following grounds:

[T]he Court finds that there is no scientific literature drawing a direct connection between the inhalation of vapors containing AFM (or any other exposure to AFM) and the occurrence of laryngeal cancer in humans. Neither party has proffered any study, experiment, or other publication in which any exposure to AFM was found to cause laryngeal cancer in humans. Moreover, there is no scientific evidence showing that the much more potent aflatoxin B-1 causes larynx cancer in humans. Where there is no direct scientific knowledge that a particular substance causes a particular form of cancer in humans, experts must turn to

epidemiological studies, in vitro studies, animal studies, and other indirect methods in an attempt to make the connection. Here, there are no such studies in which AFM or AFB have been shown to cause cancer of the larynx.

Id. at 951-52 (emphasis in original).

In so holding, the court rejected McDougal's theory that "there is no threshold for genotoxins, in that any one molecule of such a carcinogenic mutational agent can produce alterations in genetic material leading to cancer." Id. at 958. The district court began by reviewing the Reference Manual on Scientific Evidence (Reference Manual) and other literature on the theory and noted that the "no threshold" model³ has been adopted by the Occupational Safety and Health Administration (OSHA) in its regulation of workplace carcinogens and the fact that these regulations have been upheld in federal court. Id. at 959, n.8 (quoting Public Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1498 (D.C. Cir. 1986), clarified sub nom., Public Citizen Health Research Group v. Brock, 823 F.2d 626 (D.C. Cir. 1987)). Citing to the Reference Manual, the court stated:

³In defining the no-threshold and one-hit models, the court refers to the Reference Manual:

Certain mutational events, such as those leading to cancer and some inherited disorders, are believed to occur without any threshold. In theory, the cancer-specific alteration in the genetic material of the cell can be produced by any one molecule of the mutational agent. The no threshold model led to the development of the one hit theory of cancer risk, in which each molecule of a chemical has some finite possibility of producing the mutation that leads to cancer.

Id. at 959 (quoting Reference Manual at 189, n.18).

[I]t is unlikely that any one molecule of a potentially cancer-causing agent will reach that one particular spot in a specific cell and result in the change that then eludes the body's defenses and leads to a clinical case of cancer. However, the risk is not zero. As developed during the testimony, and explored in the Sutera case, regulatory agencies employ a different perspective in setting "action levels" than do the courts in imposing tort liability. Establishing that the risk of causation "is not zero" falls woefully short of the degree of proof required by Daubert and its progeny.

Id. at 961 (quotation omitted).

The court concluded that “the ‘no-threshold’ or ‘one-shot’ theory has respectable scientific support [b]ut . . . does not provide a scientific basis for a jury to find that it was more likely than not that John McDougal's cancer was caused by AMPI's exposing him to milk contaminated with aflatoxin M-1.” Id.

The district court similarly rejected the contention that McDougal's "differential diagnoses" report significantly buttressed the causation analysis. Id. at 963. In this report McDougal pointed out that it is extremely rare for a person of his age to develop laryngeal cancer, that 75 to 90 percent of all such cancers are caused by smoking tobacco or drinking alcohol, and that he neither smokes nor drinks. See id. According to McDougal, these facts make it unlikely that his cancer was caused by factors other than exposure to AFM. See id.

The district court was not convinced that the plaintiffs had successfully ruled out other possible alternative causes such as second-hand smoke from McDougal's parents and sibling or the possibility that he was exposed through his diet to other carcinogens. Id. at 963-66. Moreover, even if they had been able to rule out other causes, the court observed that plaintiffs had not ‘ruled in’ that the toxin to which McDougal was exposed was a contributing cause of his laryngeal cancer.

The court additionally noted that even the temporal association of plaintiffs' exposure to AFM failed to give support for his causation theory. The record indicates that McDougal's cancer, when discovered, was 1.9 centimeters in size. The defendant contends that the appropriate doubling time would require 8.7 years. Plaintiffs disagreed with this theory and produced evidence that the doubling would occur within a range of 3.95 years to 5.9 years. The court resolved the dispute by observing that "the latency period cannot completely exclude the possibility of Mr. McDougal's getting his cancer by reason of his exposure to AFM while on the job. But the latency data creates one more negative for the plaintiff[s]." Id. at 975.

As a final factor weighing against admissibility, the court criticized the methodology of the plaintiffs' experts, stating that since they had failed to "identify a dosage level of AFM that is known to cause laryngeal cancer in humans . . . we are back to the temporal association: plaintiff was exposed to AFM and thereafter he developed laryngeal cancer. The plaintiff[s'] experts believe that [McDougal's] cancer was caused by AFM and, if it was, then certainly the exposure and dose were sufficient. This flawed logic is no substitute for reliable scientific proof of causation." Id. at 967.

The court concluded:

[P]roof of dosage is necessary in the case, but [the court] does not agree that the calculations of Dr. Valentine or Dr. Draughon would provide an adequate basis for a jury to determine [McDougal's] level of exposure or the dosage in this case. First, Dr. Draughon's position is, simply, that even if you accept plaintiff[s'] experts' approach and assumptions, the level of exposure to aflatoxin M-1 that they postulate has not been shown to cause laryngeal or any other cancer in humans. Second, the Court accepts Dr. Draughon's critique of plaintiff[s'] exposure and dosage calculations as accurate. . . . This finding leaves [McDougal] with clear evidence that he was exposed to some aflatoxin M-1 in the aerosol produced in the cheese-making process, but no evidence from which a

jury could rationally quantify that exposure in terms of time or amount. Nor [have] plaintiff[s] even attempted to establish the level of exposure to AFM that would cause [McDougal's] cancer. So plaintiff[s] [are] really left with [their] "one-hit" "no threshold" theory.

Id. at 982 (citation omitted).

II.

Admission of expert testimony is governed by Federal Rule of Evidence 702, which states:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702. In Daubert, 509 U.S. at 588, the Supreme Court held that, consistent with the "liberal thrust" of the Federal Rules of Evidence, this rule replaced the more rigid "general acceptance" test of Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923). The Daubert Court ruled that, consistent with Rule 702, the trial judge must ensure that any and all scientific testimony or evidence admitted is relevant and reliable before admitting it. 509 U.S. at 589. The Court continued:

[I]n order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—i.e., "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.

Id. at 590.

The focus of the district court's analysis of the proffered evidence is appropriately limited solely to principles and methodology, not on the conclusions that they generate. Id. at 595. Thus, a district court is not free to choose between the conflicting views of experts whose principles and methodology are reliable and relevant. The Court in Daubert noted that many factors will bear on the inquiry as to reliability and proceeded to make some "general observations" regarding those factors, emphasizing that the inquiry under Rule 702 is a "flexible one." Id. 593-94. These observations included whether the theory or technique can be and has been tested, whether the theory has been subject to peer review and publication, and whether the theory or technique is generally accepted. See id. However, the Court noted that there would be many instances in which there would be no publication of a reliable theory, cautioning that in some cases scientific propositions may be too new to have been published, and that this factor should not be dispositive. "A reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community." Id. at 594.

Ultimately, the Daubert Court endorsed the traditional means of testing evidence in the adversary system rather than the wholesale exclusion of evidence under an uncompromising test—" [v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. at 596.

This court has likewise made it clear that the plaintiff does "not need to produce 'a mathematically precise table equating levels of exposure with levels of harm' in order to show [plaintiff's] level of exposure to [a carcinogen], but only 'evidence from which a reasonable person could conclude that [the] defendant's [action] has probably caused' the harm about which they complain." Bednar v. Bassett Furniture Mfg. Co., 147 F.3d 737, 740 (8th Cir. 1998) (quoting Wright v. Willamette Indus., Inc., 91 F.3d 1105, 1107 (8th Cir. 1996)).

It is with these principles in mind that we analyze the exclusion of McDougal's proffered evidence for an abuse of discretion. See General Elec. Co. v. Joiner, 118 S. Ct. 512, 518 (1997). Joiner held that the abuse-of-discretion standard is the proper standard by which to review a district court's decision to admit or exclude scientific evidence. See id. In doing so, the Court rejected the contention that a more searching standard of review should be given to decisions to exclude proffered expert testimony where, as here, the decision results in the granting of summary judgment and is thus "outcome determinative." Id. at 517.

III.

The essence of the district court's decision is that even though a single molecule of AFM could cause McDougal's laryngeal cancer, the possibility of that happening in a case with such low level exposure⁴ is so slight that the expert testimony that the AFM caused McDougal's cancer should be rejected. This is true, the district court says, because there are no studies or anecdotal evidence showing that AFM at the levels shown to exist here has caused cancer in humans.

One of the difficulties of the district court's opinion is that it speaks of McDougal being exposed to a single shot of AFM and states that it is exceedingly unlikely that a single shot could cause McDougal's laryngeal cancer. The undisputed evidence, however, shows that McDougal was exposed not to a single shot of AFM that exceeded the FDA standard, but that he was thus exposed on at least five occasions, and that on these occasions, he breathed in billions of molecules of AFM (Tr. at 118, 119, 761, 762, 766). It seems clear to us that the possibility of incurring laryngeal cancer from billions of molecules undoubtedly exceeds the possibility of incurring that

⁴The contaminated truckloads delivered by AMPI ranged in AFM concentration from .5 parts per billion to 5 parts per billion. Five of these were delivered to Hills Valley Foods. See note 2, supra.

disease from a single molecule. Moreover, we believe that the plaintiffs' differential diagnosis report is entitled to more weight than it was given by the district court. The facts are that McDougal was only 21 years old at the time of his exposure, laryngeal cancer is very rare among individuals of that age (see Appellant's App. at 31), and McDougal neither smoked nor drank, see Associated Milk Producers, 22 F. Supp.2d at 963. On these facts, some weight must be given to the probability that he contracted laryngeal cancer from the AFM. In light of the fact that McDougal presented evidence that the latency period of his cancer may comport with the development of that cancer as a result of exposure to the AFM-contaminated milk, the probability that he contracted his cancer as a result of his exposure to AFM-contaminated milk takes on additional weight.

Thus, our question is: Did the district court judge between the conflicting conclusions of the parties' expert witnesses or did he reject the testimony of plaintiffs' experts because under Daubert it was neither reliable nor relevant? While the line may be easy to draw in some cases, it is more difficult here, and the difficulty is compounded by the fact that at one point during her testimony Dr. Draughon, the defendant's expert relied on by the district court, stated:

Q. Given the articles that you've reviewed and Mr. Davidson's questions to you, your experience, and your review of all the literature, do you believe that Mr. McDougal's exposure to aflatoxin M1 was the cause of his laryngeal cancer?

A. I guess based upon my years of experience of working with aflatoxins and my knowledge of the literature and the things that we've talked about, I do not think that the aflatoxin M1 in the aerosol contributed to his laryngeal cancer as a sole contributor. And I don't think that eating the cheese did. The levels there are so small, I mean we are talking of .04, .08 nanograms per week. And I gave some examples of how much he would have to drink as far as milk.

Tr. at 162-63 (emphasis added). Had this testimony stood alone, our task would be immeasurably easier, as Arkansas law would hold the defendant responsible even though the AFM was a contributing rather than the sole cause of McDougal's cancer. See Jackson v. Anchor Packing Co., 994 F.2d 1295, 1303 (8th Cir. 1992) (plaintiffs in Arkansas must show "that more likely than not their exposure to a particular defendant's product was a substantial factor in producing their injuries"). However, if one reads Dr. Draughon's testimony in its entirety, as we must, it is clear that her opinion is that McDougal's exposure to the AFM-contaminated milk was neither the sole nor contributing cause of McDougal's laryngeal cancer primarily because the levels of AFM in the aerosolized milk were not high enough to cause cancer.

In our view, the scales are tipped in favor of affirming the district court because we are instructed by General Electric that we are to review the district court's decision for an abuse of discretion. The following findings support the view that the district court did not abuse its discretion:

- The plaintiffs' experts have no scientific knowledge or information as to the level of AFM exposure that would subject a person who breathes in an aerosolized milk containing AFM to an appreciable risk of laryngeal cancer. See Associated Milk Producers, 22 F. Supp.2d at 983.⁵
- There are no scientific studies or medical literature that show any correlation between AFM and laryngeal cancer. Id. In this regard, we note that Daubert makes it clear that the existence of such studies or medical literature is not a sine qua non for imposing liability on defendant; but as the opinion also makes clear, they are a factor.

⁵The district court used the words "or any risk," but it is not necessary for this court to go that far to sustain the district court's opinion.

- The Hayes and Olsen studies on which the plaintiffs' experts rely do not support a finding that AFM at the levels found here can cause laryngeal cancer. Id. As the district court points out, Dr. Valentine, who testified with respect to these studies, stated that neither he nor the authors of the paper found statistical evidence to support this view.
- Plaintiffs did not produce evidence from which a reasonable person could conclude that McDougal's inhalation of AFM suspended in aerosolized milk probably caused his laryngeal cancer. Id. He noted that none of the plaintiffs' experts based their opinions on any pre-litigation research on aflatoxins done by them, that none were oncologists, that none examined or treated McDougal, and that McDougal's treating physician was not called as a witness for the plaintiffs. Id. at 984.

Conclusion

We have noted in our opinion that this is a difficult case; and we have pointed out that a district court is not to judge the validity of competing conclusions of expert witnesses, but rather is to limit its gate-keeping role to determining whether the expert testimony offered by the parties meets the Daubert standards of reliability and relevance. Moreover, we have cautioned that the district court may not rely solely on the lack of published studies supporting an expert's conclusions because in some cases scientific propositions may have been too new to have been published or tested. On balance, however, we believe that the district court did not abuse its discretion here in excluding the testimony of the expert witnesses offered by the plaintiffs. We therefore affirm the decision of the district court.

A true copy.

Attest.

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.